

Correspondence:

Mark R Hunter CRNI, RN.
Senior Clinical Manager/ Clinical Development
Global Infusion Systems
Baxter Healthcare Corporation
25212 W. Illinois Route 120
Round Lake, Ill 60073
(847) 270-5873
(847) 270-4475 (FAX)

cc

Deborah K. Williams
Director of Public Policy
Baxter Healthcare Corporation
(202) 508 8206
(202) 508 8201 (FAX)

As a long-standing industry partner within the healthcare community, Baxter Healthcare Corporation (Baxter) would like to take this opportunity to comment on the Centers for Disease Control and Prevention (CDC) Draft *Guidelines for the Prevention of Intravascular Catheter-Related Infections*. In the section entitled “Replacement of Administration Sets”, starting at line 1042, the Draft Guidelines state “*In patients not receiving blood, blood products or lipid emulsions, replace administration sets, including secondary sets and add-on devices, no more frequently than at 96-hour intervals, [313] but at least every 7 days [255, 314-316]. Category IA*”. Baxter disagrees with the recommended change in upper and lower administration set replacement intervals.

The evidence cited to support changing the lower limit of the replacement interval all demonstrated no increase **or decrease** in infection risk between 72 hours and 96 hours. This would mean that these studies support the previously published guidelines of “no sooner than 72 hours”. For the proposed upper limit for replacement interval, none of the references cited support the “*at least every 7 days*” recommendation, in fact one article contradicts this recommendation by stating changes should not exceed 4 days [316].

Only 3 of the cited studies investigated tubing changes at 96 hours, however it is not clear how the IV tubing was utilized in the studies (i.e., gravity infusion of fluids, infusion pump with fluids and multiple secondary medications). The use of administration sets with multiple variables should be studied to not only identify whether there is an increased risk of infection but also determine whether functionality of the administration sets is possible in scenarios that could occur during a 96 hrs period. This testing would need to look at multiple areas including but not limited to:

- Pump/tubing interface
- The bag spike
- Roller clamp
- Flow rate accuracy
- Y-site actuations
- Luer connection

The majority of the studies referenced are greater than 20 years old. Infusion therapy has increased with the introduction of new therapies and patients are also more critical. We believe much more research is required to better understand the impact of changing these recommendations across all therapy areas and clinical scenarios. This research would need to demonstrate consistently reduced infection rates prior to recommending a change in the previously published set change interval.

Baxter hereby recommends that “*no more frequently than at 96-hour intervals*” be changed back to the existing 2002 Guidelines for the Prevention of Intravascular Catheter-Related Infections which is supported by the studies cited. Baxter also hereby recommends that “*but at least every 7 days*” be stricken and replaced with “*and in accordance with manufacturer’s labeled use(s) and directions*”.

Industry utilizes new guidelines and standards to direct them in testing of current and new products to ensure safety and efficacy. Industry would need significant time to complete testing and regulatory submission of thousands of current products to comply with this recommendation in the “Replacement of Administration Sets” portion of the Draft Guidelines.

References:

Maki DG, Botticelli JT, LeRoy ML and Thielke TS. Prospective study of replacing administration sets for intravenous therapy at 48- vs 72-hour intervals. 72 hours is safe and cost-effective. JAMA 1987;258:1777-81

Gillies D, O’Riordan L, Wallen M, Morrison A, Rankin K and Nagy S. Optimal timing for intravenous administration set replacement. Cochrane Database Syst Rev 2005;CD003588

Sitges-Serra A, Linares J, Perez JL, Jaurrieta E and Lorente L. A randomized trial on the effect of tubing changes on hub contamination and catheter sepsis during parenteral nutrition. JPEN J Parenter Enteral Nutr 1985;9:322-5

Snydman DR, Donnelly-Reidy M, Perry LK and Martin WJ. Intravenous tubing containing burettes can be safely changed at 72 hour intervals. Infect Control 1987;8:113-6

Josephson A, Gombert ME, Sierra MF, Karanfil LV and Tansino GF. The relationship between intravenous fluid contamination and the frequency of tubing replacement. Infect Control 1985;6:367-70